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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,665	05/03/2006	Won Kook Moon	DI-009	4344

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1655	

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10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,665	MOON ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are presented for examination on the merits.

FOREIGN PRIORITY

Although Applicants have claimed foreign priority to KR20030078503, an English translation of this document has not been received. Therefore, the effective filing date of the current application for prior art purposes is 02 November 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating ischemic brain disease/stroke, does not reasonably provide enablement for the treatment and prevention of any and all brain diseases caused by degeneration, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have reasonably described/disclosed that the instantly claimed composition comprising a grape seed extract is useful for treating ischemic brain disease/stroke. However, the claims (see e.g. claims 2 and 6) encompass using the claimed composition comprising grape seed extract for treating and preventing any and all brain diseases caused by degeneration. Applicants have not demonstrated that the

instantly claimed composition is effective in treating or preventing any and all brain diseases caused by degeneration, including, for example, Alzheimer's disease. The term "prevention" is understood in the art to encompass total protection from disease or injury. Thus, given the high level of required effect, a high level of evidence showing prevention is also required. The instant specification, however, fails to teach that the administration of the instantly claimed composition is able to treat the vast number of symptoms associated with all degenerative brain diseases, including Alzehiemer's disease, and in no way demonstrates prevention of all such diseases or disorders.

An example of a degenerative disease, Alzheimer's disease is characterized by changes in permeability of the blood brain barrier; see Anderson (U.S. Patent 5,589,154), particularly column 6 lines 27 - 40, where the reference teaches that beta-amyloid protein, the causative agent in Alzheimer's diseases, also induces vascular damage. Applicant fails to provide guidance on the treatment of these other features associated with Alzheimer's disease pathology, which would be encompassed by treatment of any and all diseases or disorders caused by degeneration, as instantly claimed. Moreover, effective therapy for the prevention of Alzheimer's has eluded researchers. As evidenced by Vickers (*Drugs Aging*, 2002, 19(7): 487-494), there is no effective treatment currently available to reverse, slow down or prevent the course of Alzheimer's disease.

Therefore, in view of the breadth of the claims encompassing a composition for preventing degenerative brain disease, the lack of adequate guidance or working examples on the use of the instantly claimed composition in treatment of all symptoms

associated with degenerative brain diseases, the lack of sufficient guidance or data or evidence supporting a preventative effect of the claimed composition in any and all degenerative brain diseases, and the unpredictability in the art of treatment of brain diseases caused by degeneration, for example, Alzheimer's disease, one of skill in the art would find that undue experimentation would be required to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the phrase "sitologically acceptable additive" in lines 1-2. It is not clear what this term means. Is this a misspelling of 'cytologically' or does this term have another meaning?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-3, 5-7, and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sekimoto (JP 11302142).

Sekimoto teaches a food composition which comprises a grape seed extract (see e.g. claim 2). Sekimoto also discloses a candy which comprises grape seed extract and vitamin C (which reads on an additive). This candy composition reads on the instantly claimed health food comprising grape seed extract with a sitologically acceptable additive. Sekimoto also teaches a solid pharmaceutical form including a tablet or capsule which contains grape seed extract (see e.g. [0036]). Sekimoto also teaches that the grape seed can be extracted using lower alcohols, water or a combination of the two as the solvent (see e.g. [0029]). Sekimoto also teaches that the grape seed extract comprises 10 to 50% by weight of the composition (see e.g. [0035]), which is within the range instantly claimed. Although Sekimoto does not teach that the composition can be used in the manner instantly claimed (as a treatment for brain degenerative disorders), the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8 and 11-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (KR20040052398).

Kim et al. teach a method of preparing a grape seed extract. Kim et al. teach that the grape seed is extracted with water at pH 8-11 (alkaline pH). Kim et al. also teaches that the mixture is centrifuged after the pH is adjusted to pH 2-4. Kim et al. further teaches that a precipitate is collected and re-suspended in alcohol, then centrifuged and that hexane (a non-polar solvent) is then added and removed, that the product is refined (which reads on further purification) and that the extract is then freeze-dried (see e.g. English translation- Claim 1). Kim et al. further teach that the extract is used in a pharmaceutical composition and in a health food with acceptable additives (see e.g. claims 6 and 8).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,4, and 7-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sekimoto (JP 11302142).

With Sekimoto discloses a grape extract composition which appears to be identical to the presently claimed extract composition and is relied upon for the reasons set forth above. Sekimoto also disclose that the grape seed extract was prepared using water as a solvent (see e.g. [0029]). Sekimoto also teaches that the extract can be further purified using well-known methods (see e.g. [0031]) and that the extract is used in dry form (see e.g. [0032]). Therefore, the instantly claimed grape seed extract composition of claims 2 and 7 is clearly anticipated by the reference and the composition of claims 4 and 8 appear to be anticipated by the reference. Even if the exact method of preparing the extract is not identical to the method instantly claimed, a person of ordinary skill in the art would reasonably expect that a grape seed extract could be produced using the commonly employed and well known techniques of aqueous alkaline extraction followed by acid neutralization, centrifugation followed by re-suspension and repeated purification followed by drying. This is especially true given the disclosure of Sekimoto that the grape seed extract can be condensed further or may be refined and further purified (see e.g. [0031]). Therefore, a person of ordinary skill in the art would be motivated to perform commonly employed purification steps and repeat them as necessary in order to obtain a dry grape seed extract as taught by Sekimoto (see e.g. [0032]) and instantly claimed. The term 'alkaline' water is given the broadest

reasonable interpretation, which means it can be even slightly above pH 7. Therefore, the use of 'alkaline' water would not materially change the composition.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' grape seed extract composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

/Patricia Leith/
Patricia Leith
Primary Examiner
AU 1655 10/12/07